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OIPE JC42
APR 07 2004
PATENT & TRADEMARK OFFICE

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April 7, 2004

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Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Group Art Unit 1645

Re: U.S. Utility Patent Application
Appl. No.: 10/668,326; Filed: September 24, 2003
For: **N-Substituted Hydromorphones and the Use Thereof**
Inventor: Donald J. KYLE
Our Ref: 1861.1640001/JMC/THN

Sir:

Transmitted herewith for appropriate action are the following documents:

1. First Supplemental Information Disclosure Statement;

2. A listing of the cited documents on Form PTO-1449 *(3 pages)*;

3. Copies of the cited documents (AL1, AR8, AS8, AT8, AR9, AS9, AT9 and AR10); and

4. One (1) return postcard.

It is respectfully requested that the attached postcard be stamped with the date of filing of these documents, and that it be returned to our courier. In the event that extensions of time are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

John M. Covert
Attorney for Applicant
Registration No. 38,759

JMC/THN/TSC:ddc
Enclosures

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OIPE JC42
APR 07 2004
PATENT & TRADEMARK OFFICE

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:	Confirmation No.: 2306
Donald J. KYLE	Art Unit: 1645
Appl. No.: 10/668,326	Examiner: To Be Assigned
Filed: September 24, 2003	Atty. Docket: 1861.1640001/JMC/THN
For: **N-Substituted Hydromorphones and the Use Thereof**	

First Supplemental Information Disclosure Statement

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98. The numbering on this First Supplemental Information Disclosure Statement is a continuation of the numbering in Applicant's Information Disclosure Statement filed on January 15, 2004, in connection with the above-captioned application. A copy each document is also provided.

In accordance with 37 C.F.R. § 1.98(a)(3), Applicant's undersigned representative submits the following concise explanation of the relevance of the non-English language document, Document AR8, cited on Form PTO-1449:

Document **AR8**, Freund, M., and Speyer, E., "Über die Reduktionsprodukte des Thebains," Ber. 53B:2250-2264 (1920), is in the German language. The document appears to describe dihydrocodeinone and dihydrothebaine derivatives. The document was cited in a search report by a foreign patent office in a counterpart foreign application. Submission of an English language version of the search report that indicates the degree of relevance found by the foreign office is provided in satisfaction of the requirement for a concise explanation of

relevance. 1138 OG 37, 38. Also, an unverified English language abstract of document AR8 is attached as document **AR10**.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicant has listed the publication date on the attached PTO-1449 based on information presently available to the undersigned. However, the listed publication date should not be construed as an admission that the information was actually published on the date indicated.

Applicant reserves the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

This First Supplemental Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits. No statement or fee is required.

It is respectfully requested that the Examiner initial and return a copy of the enclosed PTO 1449, and indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

John M. Covert
Attorney for Applicant
Registration No. 38,759

Date: April 7, 2004

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Washington, D.C. 20005-3934
(202) 371-2600

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FORM PTO-1449

FIRST SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

IPE JC42 APR 07 2004 PATENT & TRADEMARK OFFICE

ATTY. DOCKET NO.	APPLICATION NO.
1861.1640001/JMC/THN	**10/668,326**
FIRST NAMED INVENTOR	
Donald J. KYLE	
FILING DATE	ART UNIT
September 24, 2003	**1645**

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA						
	AB						
	AC						
	AD						
	AE						
	AF						
	AG						
	AH						
	AI						
	AJ						
	AK						

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL1	EP 0 306 575 A1	03/15/1989	Europe			Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	8	Freund, M., and Speyer, E., "Über die Reduktionsprodukte des Thebains," *Ber. 53B*:2250-2264, Wiley-VCH Verlag GmbH & Co. (1920).
	AS	8	Rapoport, H., *et al.*, "The Preparation of Some Dihydro Ketones in the Morphine Series by Oppenauer Oxidation," *J. Org. Chem. 15*:1103-1107, American Chemical Society (1950).
	AT	8	Small, L., *et al.*, "The Addition of Organomagnesium Halides to Pseudocodeine Types. II. Preparation of Nuclear Alkylated Morphine Derivatives," *J. Am. Chem. Soc. 58*:1457-1463, American Chemical Society (1936).

EXAMINER	DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

FORM PTO-1449 **FIRST SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**	ATTY. DOCKET NO. **1861.1640001/JMC/THN**	APPLICATION NO. **10/668,326**
	FIRST NAMED INVENTOR **Donald J. KYLE**	
	FILING DATE **September 24, 2003**	ART UNIT **1645**

PTO JC42 APR 07 2004 PATENT & TRADEMARK OFFICE

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EXAMINER INITIAL		DOCUMENT	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	9	Small, L., *et al.*, "The Addition of Organomagnesium Halides to Pseudocodeine Types. IV. Nuclear-Substituted Morphine Derivatives," *J. Org. Chem.* 3:204-232, American Chemical Society (1938).
	AS	9	Database CA 'Online!, Chemical Abstracts Service, Columbus, OH, Accession No. 65:47914, Abstract for Seki, I., "Morphine Alkaloids and Related Compounds. XIV. Preparation of 6-aminohydrophenanthrenes from Hofmann Degradation Products of Morphine Alkaloids," *Chem. Pharm. Bull. 14*:453-461 (1966).
	AT	9	International Search Report for International Application No. PCT/US03/29876, mailed on March 2, 2004, The Hague, Netherlands.

EXAMINER	DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

FORM PTO-1449 **FIRST SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**	ATTY. DOCKET NO. **1861.1640001/JMC/THN**	APPLICATION NO. **10/668,326**
	FIRST NAMED INVENTOR **Donald J. KYLE**	
	FILING DATE **September 24, 2003**	ART UNIT **1645**

PTO/SB/08A (08-03)
Approved for use through 07/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
Substitute for form 1449/PTO

IPE JC42 APR 07 2004 PATENT & TRADEMARK OFFICE

U.S. PATENT DOCUMENTS

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FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	10	Database CA 'Online!, Chemical Abstracts Service, Columbus OH, Accession No. 1921:7163, Abstract for Freund, M., *et al.*, "Reduction products of thebaine," *Ber. 53B*:2250-2264, Wiley-VCH Verlag GmbH & Co. (1920).
	AS		
	AT		

EXAMINER	DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.